IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA SHREVEPORT DIVISION

In Re: Morris & Dickson Co., LLC v. Jefferson B. Sessions, III, et al.	Case No. 5:18-cv-00605 (EEF-MLH)

DECLARATION OF KENNETH A. WEINSTEIN
May 15, 2018

I. Qualifications and Experience

1. My name is Kenneth A. Weinstein. I am a Vice President of Analysis Group, Inc. ("AGI"), located at 111 Huntington Avenue, Fourteenth Floor, Boston, Massachusetts, 02199. AGI was established in 1981 and is an international economics consulting firm with a staff of over 800 professionals. I have been employed by AGI since 2010, and also worked at AGI from 2003 to 2006. As described in my curriculum vitae (Appendix A), I received an A.B. with honors from Harvard University in applied mathematics with a sub-field of economics. In 2008, I received an M.B.A. from the MIT Sloan School of Management.

2. Through my consulting projects at AGI, my other work experience, and my academic studies, I have developed expertise in applying statistical methods to large and complex databases in both health care and other industries. Most relevant to this matter, I have extensive experience leading consulting engagements focused on the statistical analysis of data related to the distribution of controlled substances. I have worked on such projects continuously since 2011, and am currently assisting clients at every level of the supply chain for controlled substances: manufacturers, distributors, and pharmacy chains. I have developed real-time Suspicious Order Monitoring algorithms for large pharmaceutical distributors, prepared statistical analyses to identify unusual dispensing at the pharmacy and prescriber level, and assisted with loss prevention efforts based on inventory data. I have presented statistical analyses to senior government officials, including those at the Drug Enforcement Administration ("DEA"), the Department of Justice, various Offices of the United States Attorneys, and various State Attorneys General.

3. I have published articles in *Law360* regarding Suspicious Order Monitoring and changes to opioid regulations. To enhance my knowledge on these topics, I have attended conferences and symposia hosted by the Healthcare Distribution Alliance, the American Society for Pharmacy Law, and the American Conference Institute.

II. Allegations and Assignment

4. I understand that on May 2, 2018, DEA issued an Order to Show Cause and Immediate Suspension of Registration ("ISO") to Morris & Dickson Co., LLC ("Morris & Dickson"). In its ISO, DEA alleges that Morris & Dickson "has failed to maintain effective controls against the diversion of controlled substances," and has "further failed to identify and report suspicious orders to DEA."[1] DEA concludes that in light of these alleged failures, "[Morris & Dickson's] continued operation poses an 'imminent threat to public health or safety.'"[2]

5. I have been retained by Morris & Dickson to review the statistical analysis relied upon by DEA in its ISO issued to Morris & Dickson, and in particular the statistical analysis used by DEA to identify "unusually large orders" of oxycodone and hydrocodone that DEA alleges "should have been identified as potentially 'suspicious' within the meaning of 21 C.F.R § 1301.74(b)."[3] Prior to being retained in this matter on May 10, 2018, I had no prior engagements with Morris & Dickson. AGI is being compensated for my time spent on this matter at an hourly rate of $540. This compensation is not contingent on the nature of my findings or on the outcome of the proceeding.

6. I have been provided with materials from the Partial Administrative Record furnished by DEA on May 10, 2018, including its analysis of orders from January 2014 to September 2017. I also have been provided with company sales records from January 2014 to March 2018 for the eight customers named by DEA in the ISO. Appendix B lists the materials that I intend to rely upon in my testimony. If, after this declaration is filed, additional materials are provided to me that I intend to rely upon in my testimony, I will supplement Appendix B.

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[1] ISO, ¶ 21.

[2] ISO, ¶ 101.

[3] ISO, starting at ¶ 18; M&D_DEA 0000017-0000018; MorrisDickson Oxy MultiIQR Summary.xlsx; MorrisDickson Hydro MultiIQR Summary.xlsx. Per the cited regulation, "[s]uspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

III. Summary of Conclusions

7. Based on review of the materials provided to me, I intend to testify that DEA's approach in identifying potentially suspicious orders has significant statistical and conceptual flaws. These flaws render the approach unreliable for its stated purpose in the ISO, namely to identify "unusually large" orders that "should have been identified as potentially 'suspicious'" and then reported by Morris & Dickson.[4]

8. Specifically, my testimony will focus on three issues: A) DEA incorrectly implemented the Tukey method for identifying statistical outliers, leading to an over-identification of orders as "unusually large"; B) DEA's approach relies on data not available to Morris & Dickson at the time orders were made, and thus cannot be used to show that Morris & Dickson should have identified those orders as unusually large; and C) DEA's approach does not take into account ordering and inventory practices in the context of the pharmaceutical distribution business, and thus inappropriately identifies orders as unusual. Without taking into account the other flaws in DEA's analysis, I have assessed the combined impact of the first two issues on DEA's approach to "unusually large" oxycodone and hydrocodone orders in 2017, and find that *over 70 percent* of these orders would not have exceeded a threshold based on my limited adjustments to DEA's method. Given that DEA has failed to appropriately consider the context of the pharmaceutical distribution business in its application of its statistical method, even the roughly 30 percent of DEA-identified orders that remain would not necessarily be identified as "unusually large" by an appropriately applied method. Even if they were, many might not be determined to be suspicious upon review. Each of the three issues is further discussed below.

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[4] ISO, ¶ 18. In addition to its identification of suspicious orders, DEA briefly describes in the ISO an analysis "to identify extremely large monthly pharmacy volume totals." Some analysis of monthly totals appears in the Partial Administrative Record. DEA does not appear to directly rely on this analysis in its conclusion that Morris & Dickson failed to meet its regulatory requirements, and does not cite the analysis in its discussion of any of the specific customers named in the ISO. However, I have reviewed the underlying calculations, and, if asked, I intend to testify that there were several significant flaws with the approach and the underlying calculations that render the analysis unreliable.

A. DEA did not correctly follow the statistical method that it claimed to use, leading to over-identification of outliers

9. In its ISO, DEA states that it used a "standard statistical method for identifying improbable events" and that, by doing so, it identified orders that are unusual "from the standpoint of generally accepted statistical analysis."[5] In the Partial Administrative Record, DEA states that "outliers were determined by Tukey Analysis . . . ."[6] I am familiar with and have applied the Tukey approach in the context of Suspicious Order Monitoring and agree that it is a standard statistical method for identifying outliers – when applied accurately and to appropriate data. However, the method applied by DEA **differs** from the method developed by Dr. John Tukey in a **key** respect. DEA's incorrect application of the Tukey approach consistently lowers the threshold for what order size would be defined as unusual, and thus increases the number of orders identified as unusual.

10. Dr. Tukey developed and published his approach as a statistical method to identify outliers within a dataset. As put forth in his 1977 book *Exploratory Data Analysis*, the Tukey approach defines a value as "far out" if it exceeds the sum of two values: 1) the 75th percentile of the observed data,[7] and 2) the interquartile range (IQR) of the observed data (i.e., the difference between the 75th percentile and the 25th percentile),[8] multiplied by three.[9] Although the Partial Administrative Record states that DEA applied the Tukey methodology in evaluating Morris & Dickson's orders, its calculation differs from this textbook definition. As described in the Partial Administrative Record ("[t]he anomaly threshold was set at three IQR greater than the *median*" [emphasis added]). I confirmed on my review of the underlying analysis that DEA

[5] ISO, ¶ 18.

[6] M&D_DEA 0000017-0000018.

[7] The 75th percentile of a distribution represents the value below which 75 percent of the data points fall.

[8] The 25th percentile of a distribution represents the value below which 25 percent of the data points fall.

[9] John W. Tukey, *Exploratory Data Analysis* (1977).

defines an outlier as the sum of: 1) the *median* of the observed data,[10] and 2) the IQR of the observed data multiplied by three.[11] Based on my review of the relevant academic literature, I have found no basis for the use of the median in place of the 75th percentile in the Tukey approach.[12] Crucially, the median (or 50th percentile) is below the 75th percentile in the vast majority of cases.[13] In mathematical terms, it is always true that:

$$\text{Median} + 3 \times \text{IQR} \leq 75^{\text{th}} \text{ percentile} + 3 \times \text{IQR}$$

and thus that:

the threshold DEA set to define an unusual order in the Partial Administrative record is **less than or equal to** the threshold DEA would have calculated had it applied the Tukey approach correctly.

11. Without taking into account any of the other flaws in DEA's approach that I summarize below, this flaw has a **significant impact** on DEA's overall results. Based on my calculations, of the 16,596 oxycodone orders identified by DEA as unusually large, more than 9,000, or nearly 60 percent, would not exceed a threshold calculated under the correct Tukey approach. Similarly, of the 6,382 hydrocodone orders identified by DEA as unusually large, more than 1,700, or over 25 percent, would not exceed a threshold calculated under the correct Tukey approach.

12. This flaw also has a significant impact on DEA's results for the eight customers named in the ISO. Again without taking into account any other flaws in DEA's approach, DEA would have

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[10] The median, or 50th percentile, of a distribution represents the value below which 50 percent of the data points fall.

[11] M&D_DEA 0000017-0000018, MorrisDickson Oxy MultiIQR Summary.xlsx, MorrisDickson Hydro MultiIQR Summary.xlsx.

[12] *See, e.g.*, David C. Hoaglin, et al., "Performance of Some Resistant Rules for Outlier Labeling," *Journal of the American Statistical Association*, Vol. 81, No. 396 (Dec. 1986), 991-999; David C. Hoaglin and Boris Iglewicz, "Fine-Tuning Some Resistant Rules for Outlier Labeling," *Journal of the American Statistical Association*, Vol. 82, No. 400 (Dec. 1987), 1147-1149; Michael Frigge, et al., "Some Implementations of the Boxplot," *The American Statistician*, Vol. 43, No. 1 (Feb. 1989), 50-54; Jacqueline M. Hughes-Oliver, "Characterizing the Behavior of Some Boxplot Rules for Outlier Detection," *Institute of Statistics Mimeo Series*, No. 2282 (Feb. 1996); Boris Iglewicz and Sharmila Banerjee, "A Simple Univariate Outlier Identification Procedure," *Proceedings of the Annual Meeting of the American Statistical Association*, Aug. 5-9, 2001.

[13] Note that it is mathematically possible for the median to be equal to the 75th percentile in a dataset with limited variation, but the median can never exceed the 75th percentile.

identified substantially fewer orders as unusually large for these customers if it had applied the correct Tukey approach. One of the customers, Hephzibah Pharmacy LLC, would not have had any orders identified as unusually large. In total, of the 584 oxycodone and hydrocodone orders identified by DEA as unusually large for these eight customers, 162, or 28 percent, would not exceed a threshold calculated under the correct Tukey approach.

B. DEA's approach relies on data not available at the time orders were made, and thus could not have been applied by Morris & Dickson to identify suspicious orders

13. Per the ISO, DEA "conducted a statistical analysis of orders for oxycodone and hydrocodone placed with M&D between January 2014 and September 2017, to identify extremely large individual pharmacy transactions and extremely large monthly pharmacy volume totals . . . ."[14] A direct basis for DEA's conclusion that Morris & Dickson failed to meet its regulatory requirements is DEA's finding that Morris & Dickson filled the orders identified by DEA as unusually large and did not report them as suspicious.[15]

14. Yet DEA's approach uses data from throughout the January 2014 to September 2017 period to calculate a single threshold for each customer above which order size should have been considered unusually large. That is, the threshold used by DEA to determine whether an order placed in January 2014 was unusually large relied on data from orders placed in September 2017. Morris & Dickson never could have derived such a threshold to compare against its orders placed in 2014, for example, because the data used to calculate the threshold did not yet exist. It is impossible for a distributor to identify an order as unusually large (and potentially suspicious) if it only appears so compared to orders that have yet not been placed at the time the order was made.

15. DEA's results for hydrocodone illustrate one reason why relying on data not available at the time an order is placed may inappropriately identify orders as unusually large. In October

[14] ISO, ¶ 18.

[15] ISO, ¶¶ 20-21.

2014, DEA reassigned hydrocodone from Schedule III to Schedule II of the Controlled Substances Act.[16] Schedule II applies the most restrictive level of regulations available for legal controlled substances. Thus, for a reason entirely out of Morris & Dickson's control, it would be reasonable to expect hydrocodone order volumes to change between 2014 and 2017. In fact, I observe that DEA's approach identified more "unusually large" orders of hydrocodone by Morris & Dickson in 2014 (208 per month) than in any other year, with only 76 per month in 2017. Total Morris & Dickson shipments of hydrocodone decreased substantially from 2014 to 2017, from approximately ten million units per month to approximately six million units per month. Under DEA's approach, orders made in 2014, when overall volume was higher, are compared with orders made in 2017, when overall volume was lower. DEA thus identifies hydrocodone orders from 2014 as unusually large based on an inappropriate comparison to orders that occurred three years later.

16. Without taking into account any other flaws in the approach, for orders in 2017, I have assessed the impact of applying DEA's approach to a dataset that is limited to orders made in the year prior to a given order date, *i.e.*, to order data that would have been available to Morris & Dickson at the time orders were placed.[17] Based on my calculations, of the 3,306 oxycodone orders identified by DEA as unusually large in 2017, nearly 600, or nearly 20 percent, would not have exceeded a threshold based on the prior year's data. Of the 682 hydrocodone orders identified by DEA as unusually large in 2017, nearly 400, or nearly 60 percent, would not exceed a threshold based on the prior year's data.

17. For orders in 2017, I have also assessed the impact of *both* applying the standard Tukey approach discussed above *and* limiting the data to orders made in the year prior to a given order date.[18] I find that of the 3,306 oxycodone orders identified by DEA as unusually large

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[16] 21 C.F.R. § 1308 [Docket No. DEA-389].

[17] More precisely, for each order in 2017 that was identified by DEA as unusually large, I have calculated the (median + 3 x IQR) based on only the orders made by the relevant customer in the prior 365 days. Based on DEA's method, I have then compared each order to this calculated value to assess if it would have been identified as unusually large.

[18] More precisely, for each order in 2017 that was identified by DEA as unusually large, I have calculated the (75^{th} percentile + 3 x IQR) based on only the orders made by the relevant customer in the prior 365 days. Based on

in 2017, more than 2,300, or *over 70 percent*, would not exceed such a threshold. Of the 682 hydrocodone orders identified by DEA as unusually large in 2017, more than 500, or *over 70 percent*, would not exceed such a threshold.

18. Modifying DEA's calculations to rely only on data from the year prior to the order date would also have a significant impact on results for the eight customers named in the ISO. Based on my calculations, of the 96 oxycodone orders identified by DEA as unusually large in 2017 for these customers, 44, or nearly half, would not have exceeded a threshold based on the prior year's data. Of the 21 hydrocodone orders identified by DEA as unusually large for these customers in 2017, only two would exceed a threshold based on the prior year's data. As above, I have also performed a calculation that determines thresholds based on the correct Tukey approach discussed above *and* compares orders to only those made in the year prior to the order date. I find that of the 96 oxycodone orders identified by DEA as unusually large in 2017 for these customers, 70, or nearly three-quarters, would not have exceeded such a threshold. I find that *only one* of the hydrocodone orders identified by DEA as unusually large in 2017 for these customers would have exceeded such a threshold.

19. Again, that Morris & Dickson filled the orders identified by DEA as unusually large and did not report them as potentially suspicious is a direct basis for DEA's suspension of Morris & Dickson.[19] It would have been impossible at the time for Morris & Dickson to apply DEA's method to identify these orders as unusual. My calculations show that, even without any other modifications to DEA's approach, a substantial number of the orders DEA identified as unusually large likely would not have been identified as such had DEA relied only on data available at the time orders were placed.

DEA's method, I have then compared each order to this calculated value to assess if it would have been identified as unusually large.

[19] ISO, ¶¶ 20-21.

C. DEA's application of Tukey to individual order amounts is not appropriate in the context of the pharmaceutical distribution business

20. DEA has issued guidance that "distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest . . . ."[20] The choice of what data to consider for analysis—what information forms "the totality of the circumstances"—goes hand-in-hand with the statistical method used for calculation. The approach used by DEA to identify "unusually large" orders focuses on an extremely narrow view of the data: individual line-item order amounts placed for the same controlled substance by a given customer. Even if DEA had applied the correct Tukey approach or another generally accepted method for identifying outliers, and even if it had not relied upon data unavailable at the time orders were placed, its choice to take this narrow view of the data would lead to conceptual flaws in its results. I will discuss two salient characteristics of typical pharmacy ordering that lead to these flaws.

21. First, for a given controlled substance (*e.g.*, oxycodone or hydrocodone) there are a wide range of available formulations, which come in different package sizes. Based on the data I have reviewed, Morris & Dickson stocked and shipped items with as few as 20 units and as many as 500 units for oxycodone, and as few as 20 units and as many as 1,000 units for hydrocodone. Because pharmacies must fill the prescription for the formulation written by the physician and cannot order partial packages, they are forced to choose between the discrete package sizes available. Specific patient medical needs or insurance coverage can mandate that a pharmacy must order a package of 500 or 1,000 units to fill a single prescription. DEA's approach can and does deem orders of a single package as "unusually large" if the pharmacy more often orders smaller packages. Ordering packages of varying sizes is not an unusual pattern.

22. As an example, for Hephzibah Pharmacy, one of the customers named in the ISO, *every* order identified by DEA as "unusually large" was an order of a *single* 500-pill package of oxycodone

[20] Letter from Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, to DEA Registrants (September 27, 2006), 3. See Exhibit 1.

5mg or 10mg combined with acetaminophen. Because most of Hephzibah Pharmacy's other oxycodone orders were for 100-pill packages of different formulations of oxycodone (*e.g.*, oxycodone 10mg without acetaminophen), the 500-pill orders were identified as unusual by DEA's method. From my experience analyzing pharmacy dispensing and ordering data, it is not unusual for a pharmacy to need to order different formulations.

23. Second, DEA's focus on individual order sizes fails to take into account that pharmacies' ordering patterns reflect their approach to managing inventory. Pharmacies often maintain regular ordering schedules and may occasionally change schedules for logistical reasons. If a pharmacy changes to a less frequent schedule (*e.g.*, from ordering twice per week to once per week), it will likely place larger individual orders with no change to the overall volume it orders or dispenses over time. As a simple example, a pharmacy that orders 100 units twice per week and then begins to order 200 units once per week after a schedule change has not exhibited ordering activity that could reasonably be considered suspicious. Yet DEA's approach would compare the 200-unit orders to the 100-unit orders without any other context. DEA's approach even considers each order placed on the same day separately, and some pharmacies order multiple times per day. Thus, at the extreme, DEA's method could identify "unusually large" orders for a pharmacy that is shipped the same total amount by Morris & Dickson each day, but varies in the number and size of its individual orders throughout the day.

24. Pharmacies may also place a few large "stocking" orders on a periodic schedule, along with smaller orders when they run out of stock or patients request prescriptions for formulations that the pharmacy does not typically keep in stock. Such a pharmacy could, for example, place one stocking order for 1,000 units each month, and many smaller orders for 100 or 200 units as needed. A pharmacy managing inventory in this way could follow the same pattern and order nearly the same total amount each month. Yet under DEA's approach, the pharmacy could have many of its regularly scheduled 1,000-unit orders deemed "unusually large" relative to the 100-unit and 200-unit orders.

25. The data used in DEA's analysis and available to me do not provide important elements of the context described above, namely the specific formulations required by patients, the available

package sizes for those formulations, and the inventory practices of Morris & Dickson's customers. However, as a simple assessment of the potential impact of these issues, I have analyzed the number of orders identified by DEA as "unusually large" that were for 500 units of oxycodone or for 1,000 units of hydrocodone, *i.e.*, for the largest available package size that pharmacies may have been required to order to fill a single prescription. Of the 16,596 oxycodone orders identified by DEA as unusually large, more than 7,500, or nearly half, were for 500 units. Of the 6,382 hydrocodone orders identified by DEA as unusually large, more than 400, or over six percent, were for 1,000 units. Thus it appears that an alternate approach, either not based on individual order size or taking the considerations above into account, would likely have differed substantially from DEA in its results.

D. DEA's statistical analysis does not show that there is an imminent threat resulting from Morris & Dickson's distribution of controlled substances

26. I understand that a key consideration in whether an immediate suspension order is warranted is whether DEA has sufficiently proven that there is an "imminent threat to public health or safety." From my review of the Partial Administrative Record, I do not believe that DEA's statistical analysis has demonstrated an imminent threat, nor could it form a reliable basis for such a conclusion.

27. To justify its conclusion, DEA emphasizes that Morris & Dickson has continued to ship controlled substances in 2018 to certain of the customers named in the ISO. Using data through March 2018, I have assessed whether, per DEA's own calculations without modification,[21] any of the orders placed by these customers in 2018 exceeded the level defined by DEA as unusually large. I find only 20 such individual orders for oxycodone, placed by three of the customers, and only five such individual orders for hydrocodone, placed by two of the customers. Per the ISO, under DEA's approach such orders should only have been identified

[21] To identify "unusual" order size for these customers in 2018, I have relied upon the calculations provided by DEA for January 2014 through September 2017. Note that such calculations were provided for seven of the eight customers, but not for Wallace Drug Company Inc. Also, note that the data relied upon by DEA through September 2017 are not identical to the company sales data upon which I rely for analysis through March 2018.

as "potentially 'suspicious.'"[22] Thus, even had Morris & Dickson applied DEA's flawed approach and identified these orders as exceeding a threshold, upon review and investigation Morris & Dickson might reasonably have determined that these 25 orders were not suspicious and thus not faced any requirement to report them.

28. I have also assessed the recent trends in Morris & Dickson's shipments of oxycodone and hydrocodone to the eight named customers and overall. Relying on Morris & Dickson sales data for the eight customers, I find that the monthly average of Morris & Dickson's total shipments to these customers decreased by 28 percent from 2017 to 2018 for oxycodone, and by three percent for hydrocodone.

29. Finally, using the data provided by DEA through September 2017, I have assessed the trends in Morris & Dickson's total sales of oxycodone and hydrocodone. In the most recent years available, I find that the monthly average of Morris & Dickson's total shipments decreased by seven percent from 2016 to 2017 for oxycodone, and by 16 percent for hydrocodone.

30. For all the reasons discussed above, DEA's approach does not form a reliable basis that these 25 orders should have even been identified by Morris & Dickson as unusually large. DEA's approach suffers from statistical and conceptual flaws and it would not have been possible for Morris & Dickson to apply DEA's approach at the time. Further, making individual corrections for each of the flaws I have discussed would lead to a substantial reduction in the number of orders identified by DEA. Thus, I conclude that DEA's statistical analysis is not a rational or valid basis on which DEA should have relied in concluding that Morris & Dickson's continued registration poses an imminent threat to public health or safety.

[22] ISO, ¶ 18.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on May 15, 2018

Kenneth A. Weinstein

Kenneth A. Weinstein

APPENDIX A

CURRICULUM VITAE

KENNETH A. WEINSTEIN
Vice President

Phone: 617 425 8192
Fax: 617 425 8100
kenneth.weinstein@analysisgroup.com

111 Huntington Avenue
14th Floor
Boston, MA 02199

Mr. Weinstein specializes in the application of quantitative methods to real-world problems involving decision-making, strategy, risk management, and litigation. His work at Analysis Group builds on his prior experience, which includes contributing to economics research on 401(k) savings behavior, forecasting consumer demand at Zipcar, and advising foundations and government agencies on how to track and interpret data. At Analysis Group, he has managed the analysis of large transaction-level and claims databases. To help mitigate the risks associated with distributing controlled substances, he has assisted several clients in building algorithms for real-time Suspicious Order Monitoring, for periodic review of unusual dispensing at the pharmacy or prescriber level, and for loss prevention based on inventory data. He has developed flexible damages models used to negotiate high-stakes settlements in litigation related to the False Claims Act, kickbacks, intellectual property, and controlled substance regulation. Mr. Weinstein also has extensive experience supporting leading academic experts, working with cross-functional client teams, and presenting analytical results to top executives and government officials, including those at the Drug Enforcement Administration, Offices of the United States Attorneys, and State Attorneys General.

EDUCATION

M.B.A.	MIT Sloan School of Management
A.B.	Applied mathematics, subfield economics *(cum laude)*, Harvard University

PROFESSIONAL EXPERIENCE

2010-Present	Analysis Group, Inc. *Vice President (2017-Present)* *Manager (2013-2016)* *Associate (2010-2012)*
2008-2010	The Bridgespan Group *Consultant*
2007	Zipcar *Summer Analytics Consultant*
2003-2006	Analysis Group, Inc. *Senior Analyst (2005-2006)* *Analyst (2003-2004)*
2001-2002	National Bureau of Economic Research *Research Assistant to Professor David Laibson*

SELECTED CONSULTING EXPERIENCE

- **Support of pharmaceutical manufacturers, distributors, and pharmacy chains in strategic risk management for controlled substances**
  - *Development and implementation of Suspicious Order Monitoring algorithms to mitigate risk for distributors of controlled substances.* Developed real-time monitoring algorithms for clients to fulfill DEA regulations by monitoring the distribution of controlled substances for order of unusual size, frequency, or pattern.
  - *Development and implementation of store- and prescriber-level risk algorithms for pharmacy chain to identify potentially inappropriate dispensing of controlled substances.* Assessed risk factors associated with diversion and abuse of controlled substances and developed methodology to identify these factors in large dispensing databases. Developed and implemented quarterly algorithms to identify highest-risk pharmacies and prescribers.

  Led analysis of historical data to determine appropriate statistical approaches, testing of potential methods on actual client data, presentation to and training of client staff in algorithm methods, and eventual handoff to internal technology groups for long-term implementation and maintenance of algorithms. Presented on behalf of clients to officials from the Drug Enforcement Agency, Department of Justice, and State Attorneys General offices.

SELECTED LITIGATION CASE EXPERIENCE

- **Government investigations concerning prescription drug and medical device marketing practices, including the following:**
  - AzaSite/Merck (Southern District of New York)
  - Dermagraft/Shire Regenerative Medicine (Middle District of Florida, Washington D.C.)
  - Eye care products/Allergan (Eastern District of Pennsylvania)
  - Lialda, Pentasa/Shire (District of Massachusetts)
  - NovoSeven/Novo Nordisk (District of Maryland)
  - Risperdal/Johnson & Johnson (Eastern District of Pennsylvania)
  - Adderall, Daytrana, Vyvanse/Shire (District of Massachusetts)

  Evaluated alleged conduct, quantified relevant sales, and assessed the causal connection, if any, between allegations in the case and sales at issue using economic, biostatistical, and epidemiologic approaches.
- **Government investigations concerning distribution and dispensing of controlled substances**
  Provided statistical expertise to counsel on rebutting government's proposed causation and damages models. Prepared alternative damages models and presented models to government investigators.
- ***DEA v. Holiday C.V.S., L.L.C., d/b/a CVS Pharmacy #219 and #5195***
  Supported expert declarations on behalf of CVS in administrative proceedings before the Drug Enforcement Administration. Testimony included attention to dispensing patterns of certain controlled substances.

- ***Louis Vuitton Malletier, S.A. vs. Hyundai Motor America***
  Supported damages expert in case regarding the infringement and dilution of Louis Vuitton's trademark. Designed methodology for estimating the impact of the misuse of the trademark in Hyundai's national television advertising.
- **Other litigation assignments**
  - Supported economic expert in case regarding alleged monopolistic over-pricing for pharmaceutical products in Latin America. Conducted analysis of price data and led research on historical economic definition of "natural price."
  - Developed a methodology to estimate damages relating to a real estate condemnation dispute, where the plaintiff alleges that he was prevented from receiving traditional financing due to the misconduct of the condemnor. Supported industry and damages experts.
  - In cases regarding allegedly inappropriate discount programs provided by pharmacy chain for government-reimbursed prescriptions, led analysis of large dispensing databases to quantify potentially inappropriate transactions.
  - Supported damages rebuttal expert in case regarding allegedly infringed patent for use of a drug as preventive treatment for specific conditions. Employed IMS data to evaluate prescription trends over time for relevant patient characteristics. Replicated and critiqued opposing experts' "stock and flow" model of patient adoption rates.

ARTICLES

"A New Standard for Suspicious Order Monitoring" with Crystal Pike and Nicholas Van Niel, *Law360*, August 21, 2017.

"Tracing The Path To Health Care Investigation Settlements" with Paul Greenberg and Crystal Pike, *Law360*, April 17, 2017

"Viewing Recent Opioid Regulations In Context," with Paul Greenberg, Crystal Pike, and Pavel Darling, *Law360*, April 1, 2016

APPENDIX B

MATERIALS RELIED UPON

Legal Documents and Partial Administrative Record

Complaint for Injunctive Relief, May 3, 2018.

M&D_DEA000001-00000705.

MorrisDickson Hydro MultiIQR Summary.xlsx.

MorrisDickson Oxy MultiIQR Summary.xlsx.

Order to Show Cause and Immediate Suspension of Registration, May 2, 2018.

Company Data

EFDEAFIL.xlsx.

ItemFamilies.xlsx.

Regulations and Guidance

21 C.F.R § 1301.74(b).

21 C.F.R. § 1308 [Docket No. DEA-389].

Letter from Joseph Rannazzisi, Deputy Assistant Administrator, Office of Diversion Control, to DEA Registrants (September 27, 2006).

Academic Literature

Michael Frigge, et al., "Some Implementations of the Boxplot," *The American Statistician*, Vol. 43, No. 1 (Feb. 1989), 50-54.

David C. Hoaglin and Boris Iglewicz, "Fine-Tuning Some Resistant Rules for Outlier Labeling," *Journal of the American Statistical Association*, Vol. 82, No. 400 (Dec. 1987), 1147-1149.

David C. Hoaglin, et al., "Performance of Some Resistant Rules for Outlier Labeling," *Journal of the American Statistical Association*, Vol. 81, No. 396 (Dec. 1986), 991-999.

Jacqueline M. Hughes-Oliver, "Characterizing the Behavior of Some Boxplot Rules for Outlier Detection," *Institute of Statistics Mimeo Series*, No. 2282 (Feb. 1996).

Boris Iglewicz and Sharmila Banerjee, "A Simple Univariate Outlier Identification Procedure," *Proceedings of the Annual Meeting of the American Statistical Association*, Aug. 5-9, 2001.

John W. Tukey, *Exploratory Data Analysis* (1977).

EXHIBIT 1

U.S. DEPARTMENT OF JUSTICE

DRUG ENFORCEMENT ADMINISTRATION

www.dea.gov

Washington, D.C. 20537

September 27, 2006

Dear Sir or Madam:

This letter is being sent to every commercial entity in the United States registered with the Drug Enforcement Administration (DEA) to distribute controlled substances. The purpose of this letter is to reiterate the responsibilities of controlled substance distributors in view of the prescription drug abuse problem our nation currently faces.

Background

As each of you is undoubtedly aware, the abuse (nonmedical use) of controlled prescription drugs is a serious and growing health problem in this country.[1] DEA has an obligation to combat this problem as one of the agency's core functions is to prevent the diversion of controlled substances into illicit channels. Congress assigned DEA to carry out this function through enforcement of the Controlled Substances Act (CSA) and DEA regulations that implement the Act.

The CSA was designed by Congress to combat diversion by providing for a closed system of drug distribution, in which all legitimate handlers of controlled substances must obtain a DEA registration and, as a condition of maintaining such registration, must take reasonable steps to ensure that their registration is not being utilized as a source of diversion. Distributors are, of course, one of the key components of the distribution chain. If the closed system is to function properly as Congress envisioned, distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as Congress has expressly declared that the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.[2]

The Statutory Scheme and Legal Duties of Distributors as DEA Registrants

Although most distributors are already well aware of the following legal principles, they are reiterated here as additional background for this discussion.

The CSA uses the concept of registration as the primary means by which manufacturers, distributors, and practitioners are given legal authority to handle controlled substances. Registration also serves as the primary incentive for compliance with the regulatory requirements of the CSA and DEA regulations, as Congress gave DEA authority under the Act to revoke and suspend registrations for failure to comply with these requirements. (Depending on the circumstances, failure to comply with the regulatory requirements might also provide the basis for criminal or civil action under the CSA.)

[1] See National Institute on Drug Abuse Research Report: Prescription Drug Abuse and Addiction (revised August 2005), available at www.drugabuse.gov/PDF/RRPrescription.pdf.

[2] 21 U.S.C. 801(2).

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Before taking an action to revoke a registration, DEA must serve the registrant an order to show cause, which advises the registrant of its right to an administrative hearing before the agency (21 U.S.C 824(c)). The CSA also gives DEA discretionary authority to suspend any registration simultaneously with the initiation of revocation proceedings in cases where the agency finds there is an imminent danger to the public health and safety (21 U.S.C. 824(d)).

DEA recognizes that the overwhelming majority of registered distributors act lawfully and take appropriate measures to prevent diversion. Moreover, all registrants - manufacturers, distributors, pharmacies, and practitioners - share responsibility for maintaining appropriate safeguards against diversion. Nonetheless, given the extent of prescription drug abuse in the United States, along with the dangerous and potentially lethal consequences of such abuse, even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm. Accordingly, DEA will use its authority to revoke and suspend registrations in appropriate cases.

The statutory factors DEA must consider in deciding whether to revoke a distributor's registration are set forth in 21 U.S.C. 823(e). Listed first among these factors is the duty of distributors to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific, and industrial channels. In addition, distributors must comply with applicable state and local law. Congress also gave DEA authority under this provision to revoke a registration based on the distributor's past experience in the distribution of controlled substances and based on "such other factors as may be relevant to and consistent with the public health and safety."

The DEA regulations require all distributors to report suspicious orders of controlled substances. Specifically, the regulations state in 21 C.F.R. 1301.74(b):

> The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

It bears emphasis that the foregoing reporting requirement is in addition to, and not in lieu of, the general requirement under 21 U.S.C. 823(e) that a distributor maintain effective controls against diversion.

Thus, in addition to reporting all suspicious orders, a distributor has a statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels. Failure to exercise such due diligence could, as circumstances warrant, provide a statutory basis for revocation or suspension of a distributor's registration.

In a similar vein, given the requirement under section 823(e) that a distributor maintain effective controls against diversion, a distributor may not simply rely on the fact that the person placing the suspicious order is a DEA registrant and turn a blind eye to the suspicious circumstances. Again, to maintain effective controls against diversion as section 823(e) requires, the distributor should exercise due care in confirming the legitimacy of all orders prior to filling.

In addition, distributors are required to file reports of distributions of certain controlled substances to the DEA ARCOS Unit, in the time and manner specified in the regulations (21 C.F.R. 1304.33). The failure to file ARCOS reports in a complete and timely manner is a potential statutory basis for revocation under section 823(e). Depending on the circumstances, the failure to keep or furnish required records might also be the basis for civil fines or criminal penalties under the CSA, as provided in 21 U.S.C. 842.

Circumstances That Might Be Indicative of Diversion

DEA investigations have revealed that certain pharmacies engaged in dispensing controlled substances for other than a legitimate medical purpose often display one or more of the following characteristics in their pattern of ordering controlled substances:

1. Ordering excessive quantities of a limited variety of controlled substances (e.g. , ordering only phentermine, hydrocodone, and alprazolam) while ordering few, if any, other drugs
2. Ordering a limited variety of controlled substances in quantities disproportionate to the quantity of non-controlled medications ordered
3. Ordering excessive quantities of a limited variety of controlled substances in combination with excessive quantities of lifestyle drugs
4. Ordering the same controlled substance from multiple distributors

A distributor seeking to determine whether a suspicious order is indicative of diversion of controlled substances to other than legitimate medical channels may wish to inquire with the ordering pharmacy about the following:

1. What percentage of the pharmacy's business does dispensing controlled substances constitute?
2. Is the pharmacy complying with the laws of every state in which it is dispensing controlled substances?
3. Is the pharmacy soliciting buyers of controlled substances via the Internet or is the pharmacy associated with an Internet site that solicits orders for controlled substances?
4. Does the pharmacy, or Internet site affiliated with the pharmacy, offer to facilitate the acquisition of a prescription for a controlled substance from a practitioner with whom the buyer has no pre-existing relationship?
5. Does the pharmacy fill prescriptions issued by practitioners based solely on an on-line questionnaire without a medical examination or bona-fide doctor-patient relationship?
6. Are the prescribing practitioners licensed to practice medicine in the jurisdictions to which the controlled substances are being shipped, if such a license is required by state law?
7. Are one or more practitioners writing a disproportionate share of the prescriptions for controlled substances being filled by the pharmacy?
8. Does the pharmacy offer to sell controlled substances without a prescription?
9. Does the pharmacy charge reasonable prices for controlled substances?
10. Does the pharmacy accept insurance payment for purchases of controlled substances made via the Internet?

These questions are not all-inclusive; nor will the answer to any of these questions necessarily determine whether a suspicious order is indicative of diversion to other than legitimate medical channels. Distributors should consider the totality of the circumstances when evaluating an order for controlled substances, just as DEA will do when determining whether the filling of an order is consistent with the public interest within the meaning of 21 U.S.C. 823(e).

We look forward to continuing to work in cooperation with distributors toward our mutual goal of preventing the diversion of pharmaceutical controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control